

## Food Ingredients of Public Health Concern

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### The “Big 8” Food Allergies

- Milk
- Eggs
- Fish (e.g. Bass, Cod or Flounder)
- Crustacean shellfish (e.g., Crab, Lobster, or Shrimp)
- Tree nuts (e.g., almonds, pecans, or walnuts)
- Peanuts
- Wheat
- Soybeans

### Examples of Food Ingredients People May be Intolerant to:

1. Lactose
2. Sulfites
3. FD&C Yellow No. 5 (Tartrazine)
4. Monosodium Glutamate
5. Gluten
6. Nitrates
7. Nitrites

## COMPARISONS

<p><u>FOOD ALLERGIES</u>            Causes immune response</p> <ul style="list-style-type: none"> <li>○ Can be <u>aggressive</u></li> </ul> <p>Response due to exposure to allergenic Ingredients  </p> <p>Harmless to some – dangerous to others</p> <p><b>NOTE:</b> The “Big 8” food allergens are good examples of some of the most common allergens of public health concern.</p>	<p><u>FOOD INTOLERANCES</u>            Often confused with allergic <u>reactions</u></p> <p>Generally do not result in life-threatening <u>reactions</u></p> <p><b>**Examples – See above list</b></p>
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## Responsibilities

### Establishments must:

- research all ingredients used in production of its products.
- determine if an ingredient may trigger food allergies in sensitive individuals.
- must employ appropriate food safety procedures – ensure ingredients added to product match the product formula.
- ensure all ingredients are properly listed on the product label.

### Establishments must also:

- prevent cross-contact between products, equipment and utensils that do and do not contain allergens; **Cross-contact could result from inadequate control or inappropriate use of ingredients of public health concern.**
- make sure the label on the products that do contain allergens has the correct declarations on it; **accidental application of inaccurate labels to properly formulated products could pose a threat to consumers sensitive to any ingredients in the formulation.**
- effectively implement the food safety system procedures, they must control allergens on an ongoing basis.

### **NOTE: Highly refined edible oils** (soybean oil and peanut oil):

- results from processing that involves de-gumming, neutralizing, bleaching, and deodorizing extracted oils. This process removes undesirable chemicals, giving a uniform color and eliminating undesired odors. This process makes the oil virtually free of allergenic proteins. This makes the refined edible oils safe for individuals in the food-allergic population to consume.
- The “cold press” extraction of oils from plant materials **may not** remove all protein. **These oils are rarely used at this time.**

**FYI** – When allergen-containing products are cooked or par-fried in highly refined edible oils, they may leave traces of allergenic proteins behind in the oil. Establishments that reuse the same oil to cook or par-fry a variety of products should consider the potential hazard such reuse might pose to food-allergic consumers.

## **Label Declarations**

**Federal Meat Inspection Act (FMIA) + Poultry Products Inspection Act (PPIA)** -> all ingredients used to formulate meat or poultry products generally must be declared in the ingredient statement on the product label.

- A product that contains ingredients that are permitted but not declared on product labeling = misbranded
- Any ingredient should be declared by its common or usual name in the ingredients statement.

## **Voluntary Statements**

The agency allows establishments to use statements on the labels of their finished products that will alert people who have sensitivities or intolerances to the presence of specific ingredients. This allows consumers to avoid those products.

Example: “Contains: milk, wheat gluten, soy” or a product label might specify – “Contains sodium caseinate (from milk) to alert milk allergic consumers that the ingredient is derived from milk.

## **Factual Labeling Statements**

These statements provide information about a product’s manufacturing environment to the consumer.

Example: “Produced in a plant that uses peanuts,” or “**may contain**” statements like, “may contain peanuts,” on meat and poultry product labeling.

**NOTE: This type of statement should only be used in cases when an establishment can show that GMPs and Sanitation SOPs cannot reasonably be expected to effectively eliminate the possibility of cross-contact of products with ingredients of public health concern.**

**These statements can only be used in cases where establishments show that adequate Sanitation SOPs cannot effectively eliminate the potential for cross-contact. The statements must be evaluated and approved by the Labeling and Program Delivery Staff (LPDS) on a case-by-case basis.**

## **Inspection Program Personnel Responsibilities**

Establishments have preventive measures and controls to address all potential chemical hazards, including food allergens and other ingredients of public health concern.

If a meat or poultry establishment ships product containing an **undeclared allergen into commerce**, its food safety system **has failed**.

Establishment may have failed due to:

- Address an allergen as a potential chemical food safety hazard in its hazard analysis
- Failed to support the decisions made in the hazard analysis
- Failed to effectively implement controls supporting the decisions made in the hazard analysis

## **Recalls**

Recalls connected to undeclared allergens may be due to reasons, including:

- Changes in ingredient suppliers
- Suppliers changing ingredient formulations
- Finished meat or poultry products in the wrong package
- Misprinted labels applied to finished meat or poultry products
- Changes to the ingredient formulation of the meat or poultry products without a corresponding change in the labeled ingredients.
- A meat or poultry product coming into contact with an undeclared allergenic ingredient not directly added to the product.

## **The Big 8 Formulation Verification Task**

This task is used to verify that:

- establishments are accurately controlling and labeling the eight most common food allergens.
- the appropriate label is the label being applied to the product.
- the applied label is consistent with the establishment's label approval on file.

FSIS Directive 7230.1, *The Big 8 Formulation Verification Task* covers how to perform this task. IPP are encouraged to review the directive and regulations prior to implementing this task. While performing the task, IPP should:

- Review records
- Observe production processes
- Respond to specific task-related questions in PHIS

This is a routine, priority 3 task that appears on a monthly basis on the PHIS Establishment Task List. It should be performed on each shift.

- After selecting a product, you should obtain the specific product formulation for that product from the establishment.
- IPP perform the Big 8 Formulation Verification task using a combination of the recordkeeping and review and observation inspection components for the verification of the selected product. Performing the task involves:
  - Reviewing product formulation records and observing product formulation process steps to verify that all ingredients used in the production of the product are consistent with the intended product formulation.
  - Reviewing the product label to verify that all ingredients used in formulating the product are declared in the ingredients statement by common or usual name and in descending order of predominance. IPP should never assume that all ingredients used in a product formulation are appropriately declared on the final meat or poultry product labels.

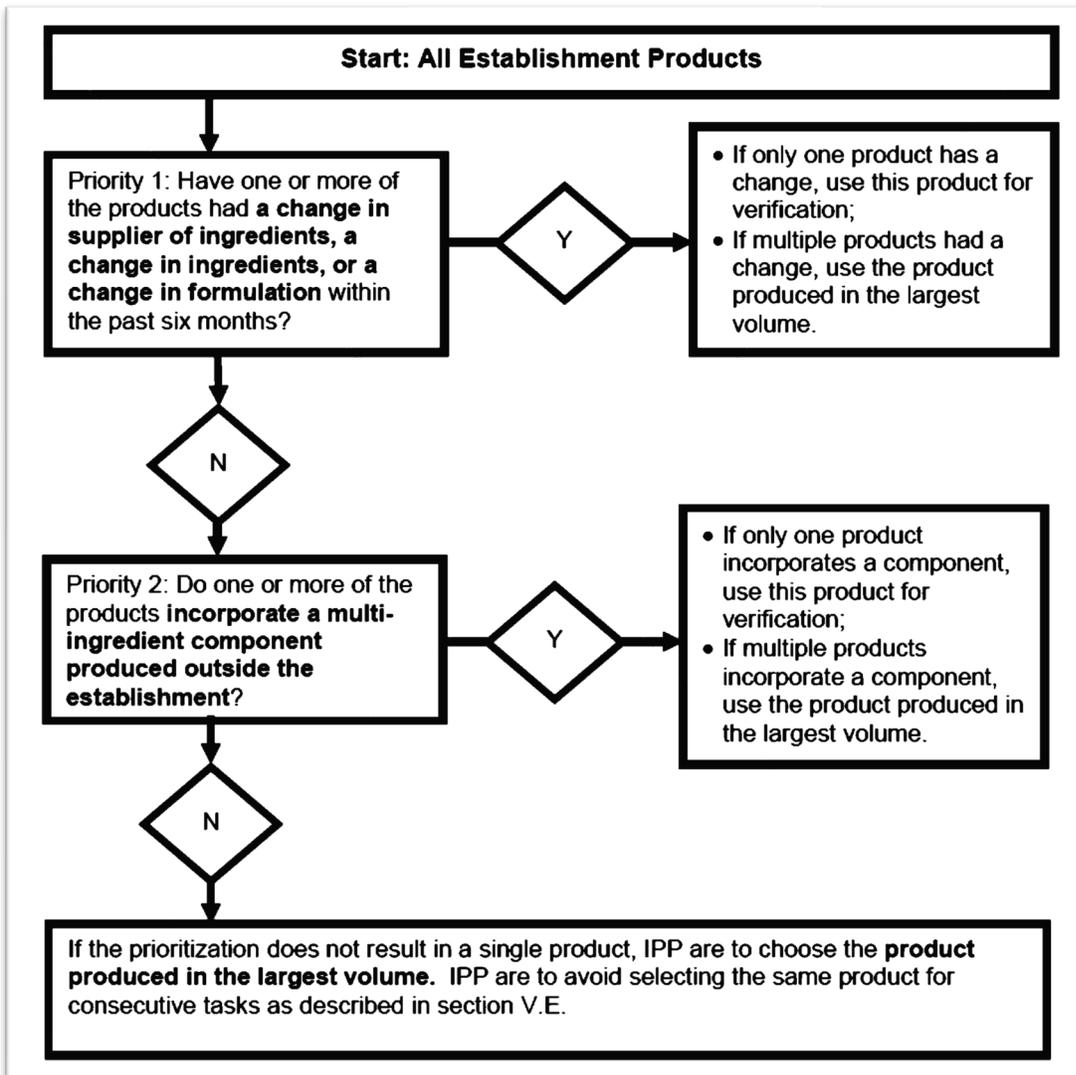
This task can be performed more often as a directed task, if there are any indications of increased risk of undeclared allergens in the establishment.

The task must be scheduled in advance. So, you can determine which products are being produced on the day you plan to perform the task.

- Coordinate with the IPP on the other shift , so that you can avoid selecting the same product for a task.
- In establishments that produce more than one product, IPP are to use the chart on the next page to prioritize a product for the verification task.
- You must determine if the establishment produces products in any of the HACCP processing categories **other than slaughter** that may contain any of the Big 8 food allergens.
- If the **establishment does produce** any products that contain one or more of the Big 8 food allergens:
  - Review the preventive and control measures developed by the establishment.
  - Verify that these measures are being implemented effectively.
  - Verify the product labels are consistent with the product formulation records.

**IPP are to apply the priority list to all products in an eligible establishment whether the establishment produces products containing a “Big 8” allergen.**

NOTE: If this task does not apply to the operations in a given establishment, based on the criteria in FSIS Directive 7230.1 -> you should **find the task on the Establishment Profile/Inspection Tasks page** for that establishment and **disable the task**.



FYI: The establishment can address the allergens within its HACCP plan, Sanitation SOPs and/or a Prerequisite Program.